

Neoadjuvant chemotherapy with a combination of pegylated liposomal doxorubicin (Caelyx) and paclitaxel in locally advanced breast cancer: a phase II study by the Hellenic Cooperative Oncology Group.

[Gogas H](#), [Papadimitriou C](#), [Kalofonos HP](#), [Bafaloukos D](#), [Fountzilas G](#), [Tsavdaridis D](#), [Anagnostopoulos A](#), [Onyenadum A](#), [Papakostas P](#), [Economopoulos T](#), [Christodoulou C](#), [Kosmidis P](#), [Markopoulos C](#).

Source

First Department of Medicine, Laiko Hospital, University of Athens, Greece. hgogas@hol.gr

Abstract

BACKGROUND:

To determine the activity and safety of the combination of paclitaxel and pegylated liposomal doxorubicin (Caelyx) in patients with locally advanced breast cancer.

PATIENTS AND METHODS:

This was a multicenter phase II study. Thirty-five newly diagnosed patients with locally advanced breast cancer were included in the study. Histological or cytological diagnosis was necessary for inclusion. Median age was 54 years (range 26-73 years). Fifteen patients were premenopausal and 20 postmenopausal. Paclitaxel was administered at a dose of 175 mg/m² and pegylated liposomal doxorubicin 35 mg/m² every 3 weeks for six cycles.

RESULTS:

Twenty-five patients (71%) responded. Six (17%) had a complete response, 19 (54%) had a partial response, four remained stable, two progressed and four were not evaluated for response due to discontinuation of chemotherapy. Three patients had a pathologically complete response. A total of 173 cycles were administered. The primary toxicity observed was skin toxicity. Grade 3 skin toxicity was noted in four patients (11%). Palmar-plantar erythrodysesthesia (PPE) grade 3 was experienced by three (9%). Two patients presented with PPE and skin toxicity. Hematological toxicities included grade 3 leukopenia in four patients (3%). Other grade 3 toxicities were uncommon and included only alopecia in 29 patients (83%). Grade 3 or 4 neurotoxicity was not observed in any patient. Dose reduction was necessary in seven patients; in six due to skin toxicity and in one due to neutropenia. Four patients discontinued treatment due to skin toxicity. There were no treatment-related deaths.

CONCLUSIONS:

The combination of pegylated liposomal doxorubicin and paclitaxel was active in locally advanced breast cancer. The primary toxicity was cutaneous toxicity and it was manageable.